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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,936	07/19/2005	Byoung-Joo Gwag	110200.404USPC	5371

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
01/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,936	GWAG ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15 and 17* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/7/08 has been entered.

2. The rejection of claims 14-17 under 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph, because the claimed invention is not supported by either a credible asserted utility for the recitation of "*preventing* neuronal cell death" is withdrawn due to the amendment of the claims.

3. The rejection of claims 14-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn due to the amendment of base claim 14 to recite specific tetrafluorobenzyl compounds.

4. Applicant's arguments filed 9/5/08 have been fully considered but they are not deemed to be persuasive.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, as it relates to compositions comprising the elected invention, BDNF.

7. Claims 14-17 are objected to for failure to claim the elected invention of BDNF of Group IIb. The generic recitation of "neurotrophin" and NGF, NT-3 and/or NT-4/5 (e.g., claims 14 & 15) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/10/08.

This application contains claims 14-17 drawn to an invention nonelected with traverse in the reply filed on 3/10/08 A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

Rejection Necessitated by Amendment of the Claims

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14, 15 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gwag et al (WO 01/79153 A1; IDS Ref #AD) and Perez-Navarro et al (2000; IDS Ref #DI).

Gwag et al teach pharmaceutical compositions comprising BAS and its derivatives (i.e., TBAS, NBAS, CBAS, MBAS, and FBAS), which are antioxidants that can attenuate NMDA neurotoxicity, and can be used to treat "neurodegenerative diseases that are accompanied by neurotoxicity" (pgs. 10, 13-14 & 27-28; as it relates to claims 14 & 17). Page 3 of Gwag further teach that Huntington's disease (HD) is a progressive neurodegenerative disease state where NMDA receptor-mediated neurotoxicity contributes to selective neuronal death in HD", and therefore, is a candidate disease state treatable with their pharmaceutical compositions. However, Gwag et al do not teach compositions comprising the neurotrophin BDNF for treating Huntington's disease, or any other neurodegenerative disease.

Perez-Navarro et al teach that the neurotrophins BDNF, NT3 and NT4/5 can be used to differentially increase survival of striatal projection neurons in a mouse model of HD where NMDA neurotoxicity is induced (e.g., pg. 2190; as it relates to claims 14 & 15), and concludes that "continuous flow of low doses of BDNF might be beneficial for the treatment of neurodegenerative disease states affecting striatal projection neurons", such as Huntington's disease (see Abstract & pg. 2198 (*pp* bridging col. 1 & 2)). Excitotoxicity, oxidative stress, etc. are disclosed by Perez-Navarro et al as mechanisms that may explain neurodegeneration in HD (pgs. 2190 & 2198 (1st col.)). However, Perez-Navarro et al do not teach compositions comprising neurotrophins and BAS derivatives for treating Huntington's disease.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant invention to complement the pharmaceutical compositions of Gwag et al with the neurotrophins BDNF, NT3 & NT4/5 of Perez-Navarro et al, because both set of compounds would be beneficial for treating NMDA receptor-mediated neurotoxicity in Huntington's disease with a reasonable expectation of success, based upon both compounds being reasonably effective in treating NMDA receptor neurotoxicity.

It is noted that MPEP 2144.06 makes clear that it is obvious to combine equivalents known for the same purpose. In particular,

> "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-7997 (toll-free).

/Robert C. Hayes/
Primary Examiner, Art Unit 1649
January 5, 2009